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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,699

04/21/2004

Karen M. Cheves

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,699	<b>Applicant(s)</b> CHEVES ET AL.	
	<b>Examiner</b> ANDREW M. GILBERT	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15, 26-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15 and 26-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed 6/30/2010.
2. Claim 15 was amended and new claims 26-34 were added.
3. Thus, claim 15 is pending for examination.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 recites that the cutting blade includes at least one surface having a series of bumps or projections. However, that subject matter is disclosed only in conjunction with a separate embodiment shown and discussed in relation to Figure 5. The independent claim 15 is directed to the embodiment shown in Figure 4 – which has an undulating cutting blade, but one free of bumps or projections. Thus, in the originally filed specification, the applicant did not disclose an undulating cutting blade *with* bumps or projections.
3. Note: with regards to claims 32 and 33 the Examiner has interpreted “textured” to mean the visual or tactile surface characteristics and appearance of something (see

Webster's dictionary definition). Thus, the undulating cutting member shown in Fig 4 inherently has a textured surface.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al (2004/0243156).

5. Claims 15, 26-33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wu et al (2004/0243156).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

6. Wu et al discloses a cutting balloon catheter (Fig 2), comprising: an elongate catheter shaft 12); a balloon (114) coupled to the shaft, the balloon having a first fully inflated configuration and a second non-inflated configuration (Fig 2-4), wherein the

balloon has a plurality of substantially smooth wings formed therein when in the second non-inflated configuration (Fig 2-4; [0030]), a metallic cutting blade (16) for severing or breaking up a lesion adhesively bonded ([0018]) to the balloon throughout the entire use of the cutting balloon catheter (Fig 2-4; Summary), the cutting blade including means for cutting having two intersecting planes which form a cutting edge, including means for gripping thereon and having a longitudinal axis (16; Fig 2-4), and having a cross-sectional shape that is substantially triangular in a plane traverse to the longitudinal axis (16; Fig 2-4); wherein the means for cutting and means for gripping are defined by a series of undulations (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42) on the cutting blade in the first fully inflated configuration; and wherein the undulations curve from side-to-side relative to the longitudinal axis in the first inflated configuration(16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42); the wings are a plurality of alternating inward/outward radial deflections in the balloon that are evenly spaced circumferentially around the balloon (Fig 3); where there are 4 wings (Fig 3); a plurality of cutting members at the inward-most positions of respective pairs of adjacent wings (Fig 3); where the wings fold over and cover the metallic cutting blade members ([0017]); the cutting blade has a textured surface (16; with regards to claims 32 and 33 the Examiner has interpreted “textured” to mean the visual or tactile surface characteristics and appearance of something (see Webster’s dictionary definition). Thus, the undulating cutting member shown in Fig 4 inherently has a textured surface).

7. However, Wu is silent regarding any undulations of the blades when the balloon is inflated. Wu discloses a cutting blade with a series of undulations curving from side-to-side relative to the longitudinal axis in the first inflated configuration (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42). The cutting members are made of a cutting structure, such as a metallic cutting blade similar to a knife, that has a rigid structure ([0018]). It would have been obvious to one of ordinary skill in the art at the time of the invention to have the metallic members maintain their undulating curves as the balloon went from the deflated to inflated configuration because the cutting member is made of a metallic material, acts like a knife and should maintain its structure between configurations to increase the surface area of the cutting member to cut the angioplasty lesion.

8. Further, Wu is distinct from the Applicant's cited reference Kelly 2005/0228343 (see Remarks, pg 5). Wu only discloses the cutting blade being metallic ([0018]); whereas, Kelly recites multiple materials of varying rigidity, including polymers (Kelly, [0013]). Further, Kelly cites that there is a joining member 38 that is elastic or pliable that joins the balloon and cutting blade; whereas Wu simply uses an adhesive. The structure and materials involved in Kelly and Wu are not structurally similar and thus the disclosure that Kelly teaches bending or flexing cutting blades is not applicable to Wu because we does not disclose bending or flexing the cutting blades. Wu discloses a metallic cutting blade that is similar to a knife. One of ordinary skill in the art at the time of the invention would have found it obvious that a metallic cutting blade that is similar

to knife would hold its structural configuration as the balloon transitions from an deflated to fully inflated configuration, thus maintaining the undulations in the fully inflated state.

### ***Response to Arguments***

9. Applicant's arguments with respect to claim 15 in view of Wu have been considered but are moot in view of the new grounds set forth above.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767

**/KEVIN C. SIRMONS/  
Supervisory Patent Examiner, Art Unit 3767**